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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/540,215 | 06/20/2005 | Gerolf Zimmermann | 00401P0004WOUS | 5244 |

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| EXAMINER | |
|---|---|
| PANDE, SUCHIRA | |
| ART UNIT | PAPER NUMBER |
| 1637 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 31 DAYS | 04/26/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/540,215 | ZIMMERMANN ET AL. | |
| | Examiner | Art Unit | |
| | Suchira Pande | 1637 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 31-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 31-61 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 31-46 and 61, drawn to methods for determining specific conditions or changes in endometrium.

Group II, claim(s) 47-57, drawn to products (primers and diagnostic kit).

Group III, claim(s) 58-60, drawn to nucleic acid sequence and markers.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Policastro et al. (1983) J. of Biol. Chem. Vol. 258: No 19, PP.11492-11499 teaches the sequence claimed in the instant application as the primer sequence SEQ ID No 3.

See the alignment below:

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Qy          1 CACTGAGGGGAGAGGACTGGGGT 23 (SEQ ID no. 3)
              |||||||||||||||||||||||
Db        371 CACTGAGGGGAGAGGACTGGGGT 393
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Thus SEQ ID no 3 of Group II invention recited in claim 47 of the instant application was already taught by prior art at the time the invention was made. Thus the primers of

Group II invention do not share the special technical features with the method of group I invention and the nucleic acid sequences and markers of group III invention. Hence unity of invention is lacking.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

**A. Species of Methods**:

a. Method for determining specific conditions or changes in the endometrium or in the epithelium of other organs (claim 31).

b. Method for prospective or retrospective diagnosis for implantation of an embryo (claim 40).

c. Method for Tumor diagnosis (claim 43)

d. Real time RT PCR method for prospective or retrospective diagnosis for implantation of an embryo and tumor diagnosis (claim 61)

**B. Species of at least two primers:**

e. at least two primers hybridizing with cDNA of at least one of β7-hCG, β6-hCG, and β6e-hCG, wherein at least one of the two primers does not hybridize with at least one of β5-hCG, β8-hCG, and β3-hCG (claim 48)

f. wherein the at least two primers comprise:

a first primer pair comprised of a first primer and a second primer wherein the first primer pair hybridizes with cDNA of β5-hCG, β8-hCG, and β3-hCG as well as β7-hCG, β6-hCG, and β6e-hCG; and

a third primer that hybridizes specifically with cDNA of β37-hCG and β6-hCG and β6e-hCG but not with cDNA of β5-hCG, β8-hCG, β3-hCG (claim 49).

g. wherein the at least two primers comprise a fourth primer that hybridizes specifically with cDNA of β5-hCG, β8-hCG, and β3-hCG but not with cDNA of β7-hCG and β6-hCG and β6e-hCG (claim 50).

h. wherein the first primer pair is selected from the group of sequences consisting of SEQ ID NO. 1, SEQ ID NO. 2, SEQ ID NO. 11 and SEQ ID NO. 14, and wherein the third primer is selected from the group of sequences consisting of SEQ ID NO. 3, SEQ ID NO. 9, SEQ ID NO. 10, SEQ ID NO. 13, and SEQ ID NO. 16 (claim 51).

**C. Species of Diagnostic Kit**

i. Kit for determining changes in uterus (claim 48).

j. Kit for prospective or retrospective diagnostic for implantation of an embryo (claim 56).

k. Kit for tumor diagnosis (claim 57).

**D. Species of Nucleic Acid Sequences and Markers**

l. SEQ ID No 7 (claim 58 in part)

m. SEQ ID No. 17 (claim 58 in part)

n. SEQ ID No 18 (claim 58 in part)

o. SEQ ID No. 5 (claims 59 and 60 in part)

p. SEQ ID No. 6 (claims 59 and 60 in part)

4. The species of methods are different methods that are designed to achieve different end results. The pair of primers are distinct nucleotide sequences hybridizing to different parts of genome as is evident from the limitations associated with them. The diagnostic kits are designed for measuring different outcomes and the markers are different molecules as each SEQ ID no is composed of different sequence of nucleotides.

**SEQUENCE ELECTION**

5. This application contains claims directed to the following patentably distinct Restriction Subgroups of the claimed invention. After election of one of the Groups above, Applicant is required to also elect a restriction subgroup. This is not a species election. Applicant will be required to cancel non-elected subject matter upon indication of allowable subject matter.

Each of the primers identified by SEQ ID nos. comprise a patentably distinct subgroup.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed Subgroup consisting of a **single** *first primer pair (Please specify two SEQ ID nos),* **single** *third primer (provide single SEQ ID no)* ***and*** **single** *fourth primer (provide single SEQ ID No)* for prosecution on the merits to which the claims shall be restricted.

Applicant is advised that a reply to this requirement must include an identification of the restriction subgroup that is elected consonant with this requirement, and a listing

of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Should applicant traverse on the ground that the Restriction Subgroups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the Restriction Subgroups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is required, in reply to this action, to elect a **single** species from each of the categories **A-D** enumerated above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande
Examiner
Art Unit 1637

TERESA E. STRZELECKA, PH.D.
PRIMARY EXAMINER
Teresa Strzelecka
4/24/07